

Remarks

Claims 1-6, 13-26, 56-61, 68-81, 109, and 111-119 are pending in this application. The subject matter of claim 82 has been incorporated into claims 1 and 56, and claim 82 has been canceled without prejudice. The subject matter of claim 110 has been incorporated into claim 109, and claim 110 has been canceled without prejudice. No new matter was added to the application by virtue of these amendments.

I. Brief History of This Application

This application was filed August 19, 2003, and is a continuation-in-part of U.S. Patent Application No. 09/596,191, filed June 16, 2000, now U.S. Patent No. 6,607,777, which claims the benefit of U.S. Provisional Application No. 60/140,280, filed June 18, 1999.

A restriction requirement was mailed on September 26, 2005, wherein restriction was required one of two groups. A species election was also required. On February 27, 2006, Applicants filed a response, wherein Group I, drawn to claims 1-26 and 56-119 was elected with traverse. A species was elected, and all the claims readable on the elected species were identified.

A first substantive Office Action was mailed on May 16, 2006. Claims 1-6, 13-16, 22-26, 56-61, 68-71, 77-82, 109-113, and 119 were rejected under 35 U.S.C. § 103(a) over U.S. Patent

No. U.S. Patent No. 3,886,299 ("Feldbrugge"); claims 17, 18, 72-73, 114, and 115 were similarly rejected over Feldbrugge and U.S. Patent No. 5,366,748 ("Villagran"); and claims 19-21, 74-76, and 116-118 were similarly rejected over Feldbrugge and Japanese Patent Document No. JP 58-28235. Further, an obviousness-type double patenting rejection was advanced, wherein the claims then under consideration were rejected as allegedly being obvious over Applicants' U.S. Patent No. 6,607,777.

Applicants filed a response on September 18, 2006, addressing each of the grounds of rejection. A terminal disclaimer was also filed for obviating the obviousness-type double patenting rejection.

A final Office Action was mailed on December 13, 2006, wherein the obviousness-type double patenting rejection was withdrawn, but, otherwise, the grounds of rejection under 35 U.S.C. § 103(a) were maintained.

Applicants filed an after-final amendment on May 25, 2007. This amendment contained a further thorough discussion of the rejections, a proposed amendment to cancel the non-elected claims, and a Declaration of Conly L. Hansen under 37 C.F.R. § 1.132. Reasons why the Declaration of Conly L. Hansen was necessary and not previously presented were given.

An Advisory Action was mailed June 13, 2007, wherein the USPTO refused to enter the cancellation of claims despite 37

C.F.R. § 1.116(b)(2), and refused to enter the Declaration of Conly L. Hansen. Applicants filed a Notice of Appeal on June 13, 2007; an Appellant's Brief under 37 C.F.R. 41.37 on November 13, 2007; and an Appellant's First Supplemental Brief under 37 C.F.R. § 41.37 on March 14, 2008.

Instead of presenting an Examiner's Answer, the next action by the USPTO was to withdraw the finality of the above-mentioned rejections, conduct a new search, and present a new non-final Office Action wherein two grounds of rejection that had been appealed were withdrawn and 10 new grounds of rejection were alleged, relying on four new references in addition to the three references previously relied on. One of the new grounds of rejection was not art-based.

II. Response to Rejections under 35 U.S.C. § 112, Second Paragraph

A. Legal Standards under 35 U.S.C. § 112, Second Paragraph

The second paragraph of 35 U.S.C. § 112 is directed to requirements for the claims:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

There are two separate requirements set forth in this paragraph:

(1) the claims must set forth the subject matter that the applicants regard as their invention; and (2) the claims must

particularly point out and distinctly define the metes and bounds of the subject matter that will be protected by the patent grant. MPEP § 2171.

With respect to the second requirement of 35 U.S.C. § 112, second paragraph, the claims must particularly point out and distinctly claim the invention.

The examiner's focus during examination of claims for compliance with the requirement for definiteness . . . is whether the claim meets the threshold requirements of clarity and precision, not whether more suitable language or modes of expression are available. . . . [The examiner] should allow claims which define the patentable subject matter with a reasonable degree of particularity and distinctness. . . . The essential inquiry pertaining to this requirement is whether the claims set out and circumscribe a particular subject matter with a reasonable degree of clarity and particularity. Definiteness of claim language must be analyzed, not in a vacuum, but in light of (1) the content of the particular application disclosure, (2) the teachings of the prior art, and (3) the claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made. If the scope of the invention sought to be patented cannot be determined from the language of the claims with a reasonable degree of certainty, a rejection of the claims under 35 U.S.C. 112, second paragraph is appropriate. *In re Wiggins*, 488 F.2d 538, 179 USPQ 421 (CCPA 1973).

MPEP § 2173.02 (emphasis in original); *In re Moore*, 169 U.S.P.Q. 236, 238 (C.C.P.A. 1971); *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 231 U.S.P.Q. 81, 94 (Fed. Cir. 1986); *Shatterproof Glass Corp. v. Libbey Owens Ford Co.*, 225 U.S.P.Q. 634, 641 (Fed. Cir. 1985).

B. Factual and Legal Analysis

The Office Action alleged that claims 1, 56, and 109 are not clear with respect to whether the recited percentages refer to the textured whey protein product or to the composition prepared prior to thermoplastic extrusion. The claims in question recited "a thermoplastic extrusion product of a composition comprising" defined ingredients. The claim make reasonably clear that it is the composition that comprises the ingredient listed in the rest of the claim. If it were the thermoplastic extrusion product that comprises the listed ingredients, then there would be no reason to mention the pre-extrusion composition. Therefore, it is respectfully submitted that a person of ordinary skill in the art would understand that it is the composition that comprises the listed ingredients. Applicants further respectfully submit that the claims set out and circumscribe a particular subject matter with a reasonable degree of clarity and particularity and that the scope of the invention sought to be patented can be determined from the language of the claims with a reasonable degree of certainty. Therefore, withdrawal of the rejection is respectfully requested.

III. Response to Rejections under 35 U.S.C. § 102

A. Legal Standards under 35 U.S.C. § 102

Before discussing rejections based upon 35 U.S.C. § 102, it is believed proper to state that to sustain a rejection under § 102 the Patent and Trademark Office must abide by the following statement of the law.

Under 35 U.S.C. § 102, anticipation requires that each and every element of the claimed invention be disclosed in a prior art reference. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1554, 220 USPQ 303, 313 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984). In addition, the prior art reference must be enabling, thus placing the allegedly disclosed matter in the possession of the public. *In re Brown*, 329 F.2d 1006, 1011, 141 USPQ 245, 249 (CCPA 1964).

Akzo N.V. v. U.S. Int'l Trade Comm'n, 1 U.S.P.Q.2d 1241, 1245 (Fed. Cir. 1986).

B. Factual and Legal Analysis

(1) Claims Rejected Over the Morimoto Reference

Claims 1-4, 13-16, 56-59, 68-71, 82, and 109-13 were rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 4,338,340 ("Morimoto").

Morimoto discloses a meat analog prepared from an aqueous protein solution comprising heat-coagulable protein. Abstr. The heat-coagulable protein in the solution is denatured before or after the intimate mixing with a starch and an alkali metal sulfite. Abstr. The moisture level of the mixture is adjusted

to a suitable level for extrusion such that a fibrous protein product having a meat-like texture is shaped and formed. Abstr.

Claims 1 and 56 have been amended to incorporate the subject matter of claim 82, namely, that the whey protein used in the composition that is subjected to thermoplastic extrusion is undenatured. Morimoto, on the other hand, requires the use of denatured protein. Abstr.; col. 2, lines 29-35; col. 3, lines 3-6; col. 4, lines 11-15. Therefore, Morimoto fails to disclose each and every element of the invention claimed in independent claims 1 and 56 and their dependent claims.

Concerning claim 109, Morimoto fails to disclose using a whey protein concentrate that contains at least about 80% by weight of protein. Morimoto merely discloses use of "milk-whey protein," whatever that is. Thus, Morimoto fails to disclose each and every element of the invention claimed in independent claim 109 and its dependent claims. Moreover, it is respectfully submitted that Morimoto fails to provide an enabling disclosure of each and every element claimed in claims 109-113, because Morimoto's disclosure of "milk-whey protein" does not place a whey protein concentrate containing at least about 80% protein in possession of the public. For these reasons, Morimoto fails to anticipate any of the rejected claims. Therefore, withdrawal of the rejection of claims over Morimoto is respectfully requested.

(2) Claim Rejected Over the Yackel Reference

Claims 109 and 116-118 were rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 4,517,218 ("Yackel").

Yackel discloses vegetable protein extrudates that imitate cooked mushrooms and shellfish products. Abstr. The extrudates are prepared by thermoplastic extrusion of proteinaceous materials that contain at least 110 parts by weight of water for each 100 parts by weight of proteinaceous material. Col. 2, lines 18-21. Proteinaceous materials include materials that contain animal, microbial, and vegetable proteins. Col. 2, lines 33-45.

Claim 109 has been amended such that the composition subjected to thermoplastic extrusion contains about 1-60% by weight of edible polysaccharide. Yackel fails to disclose this claim element. Thus, Yackel fails to anticipate claim 109 or any claim dependent on claim 109. Therefore, withdrawal of the rejection is respectfully requested.

IV. Response to Rejections under 35 U.S.C. § 103

A. Legal Standards under 35 U.S.C. § 103

Before responding directly to the issues raised by the Office Action under Section 103, the legal foundation for sustaining such a rejection will be reviewed. Briefly, an

applicant for a patent is entitled to the patent unless the application fails to meet the requirements established by law. 35 U.S.C. §§ 101, 102, 103, 112. It is the USPTO's duty to issue a patent or establish that the applicant is not entitled to a patent under the law. *In re Warner*, 154 USPQ 173, 177 (CCPA 1967), cert. denied, 389 U.S. 1057 (1968). Thus, the initial burden is on the USPTO to establish a *prima facie* case of obviousness. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988). If no *prima facie* case of obviousness is established, then a rejection under Section 103 cannot properly be sustained. *In re Oetiker*, 24 U.S.P.Q.2d 1443 (Fed. Cir. 1992). If the USPTO establishes a *prima facie* case of obviousness, then the burden of production shifts to the applicant to provide appropriate rebuttal, although the burden of persuasion always remains with the USPTO. *Id.* Such rebuttal may include arguments, amendments, and/or presentation of objective indicia of nonobviousness. However, such objective indicia are always relevant to a determination of nonobviousness whether or not a *prima facie* case of obviousness has been established. *Stratoflex Inc. v. Aeroquip Corp.*, 218 U.S.P.Q. 871, 879 (Fed. Cir. 1987). To establish a *prima facie* case of obviousness, the USPTO must show all of the limitations of the claimed invention in the prior art. *In re Ehrreich*, 200 U.S.P.Q. 504, 509-11 (C.C.P.A. 1979). The subject matter of the invention must be

considered as a whole and through the eyes of a hypothetical person of ordinary skill, not expert skill, in the relevant art at the time the invention was made. *Connell v. Sears, Roebuck & Co.*, 220 U.S.P.Q. 193, 199 (Fed. Cir. 1983). References must also be considered as a whole, including subject matter that teaches away from the invention as well as subject matter that suggests the invention, and not for their isolated teachings. *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 227 U.S.P.Q. 657, 669 (Fed. Cir. 1985). References may be combined if there would be a "reason to combine" them. *KSR Int'l Co. v. Teleflex, Inc.*, 127 S. Ct. 1727, 1740-41, 1742 (2007). That is, "a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art" because "inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known." *Id.* at 1741. In nonobviousness analysis, one must "guard against slipping into the use of hindsight" and "resist the temptation to read into the prior art the teachings of the invention in issue." *Graham*, 383 U.S. at 36, 148 USPQ at 474; *KSR*, 127 S. Ct. at 1742. Finally, all the facts in evidence are evaluated, and patentability is determined on the totality of the record. *In re Corkill*, 226 USPQ 1005, 1008 (Fed. Cir. 1985). Factual

determinations made by the USPTO must be based on a preponderance of the evidence, and legal conclusions must be correct. *In re Caveny*, 226 USPQ 1, 3 (Fed. Cir. 1985).

Pursuant to established legal authority, patentability under 35 U.S.C. § 103 requires a four-step factual analysis, which involves (1) determining the scope and content of the prior art, (2) ascertaining the differences between the prior art and the claimed inventions, (3) resolving the level of ordinary skill in the pertinent art, and (4) utilizing the objective evidence of nonobviousness that may have been presented. *Graham v. John Deere Co.*, 383 U.S. 1, 17, 148 USPQ 459, 467 (1966). After all of these factors have been considered, the ultimate legal conclusion on the issue of obviousness must be reached. With the above background in mind the rejections under 35 U.S.C. § 103 will be discussed.

B. Factual and Legal Analysis

(1) Claims Rejected Over the Morimoto and/or de Ruyter References

Claims 5, 6, 60, and 61 were rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Morimoto alone or in view of U.S. Patent No. 4,338,340 ("de Ruyter"). Claims 23-26 and 78-81 were similarly rejected as being obvious over Morimoto.

Morimoto was summarized above.

The de Ruyter reference discloses an apparatus for texturizing protein products. Abstr. The apparatus includes a screw conveyor through which a protein dough containing a heat coagulable protein is passed such that the dough is stretched during passage while being heated to a temperature above the heat coagulation temperature of the protein to provide a meat-like fiber structure wherein the fibers are aligned. Abstr.

As mentioned above in connection with the analysis of claims rejected under § 102(b), Morimoto fails to disclose or suggest each and every limitation of the invention claimed in claim 1, claim 56, and claims dependent on claims 1 or 56. Claims 5, 6, and 23-26 are dependent on claim 1, and claims 60, 61, and 78-81 are dependent on claim 56. Morimoto fails to disclose using undenatured protein in the composition that is subjected to thermoplastic extrusion. In fact, Morimoto requires the use of denatured protein in the material that is subjected to thermoplastic extrusion, thus teaching away from the presently claimed invention.

The combination of Morimoto and de Ruyter also teaches away from making the presently claimed invention. Morimoto teaches that the heat coagulable protein that is subjected to thermoplastic extrusion must first be denatured to render it "less sticky, noncohesive and water insoluble." Column 4, lines 11-15. Claims 5, 6, 60, and 61, on the other hand, are dependent

on claim 1 or claim 56, each of which contains as a limitation the use of undenatured protein. Therefore, the combination of Morimoto and de Ruyter fails to disclose each and every limitation of the presently claimed invention and teaches away from the invention as claimed.

Therefore, the rejection of claims 5, 6, 23-26, 60, 61, and 78-81 under § 103(a) over Morimoto alone or of claims 5, 6, 60, and 61 over the combination of Morimoto and de Ruyter should be withdrawn.

(2) Claims Rejected over the Feldbrugge Reference

Claims 1-6, 13-16, 22-26, 56-61, 68-71, 77-82, 109-113, and 119 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Feldbrugge.

Feldbrugge discloses dense, substantially unpuffed, fibrous products that simulate the muscle of animals or the flesh of fish. (Abstr.) These fibrous products are made by "feeding a proteinaceous dough through a heated channel of decreasing volume to simultaneously elongate and thermally coagulate the dough and then releasing the compression without forcing the dough through a die while maintaining a pressure drop below 100 psi." (Abstr.) More particularly, Feldbrugge used a Sigma mixer to mix ingredients prior to extrusion in a single screw extruder. (Col. 7, lines 30-31; col. 7, line 67, through col. 8, line 2; col. 8,

lines 14-17; col. 8, lines 55-56; col. 9, lines 2-4.) This process involved putting the dough in a heated chamber of decreasing volume. This extrusion process required compression and stretching for fiber formation. It also required the dough to show visible fibers during the mixing stage prior to extrusion. (Col. 5, lines 8-10 and 22-27.) Moreover, no exit die was used. (Abstr.; col. 2, lines 17-19; col. 3, lines 27-32; col. 7, lines 20-23.)

(a) Feldbrugge Fails To Disclose Thermoplastic Extrusion

Applicants respectfully traverse the characterization of Feldbrugge's method as involving "thermoplastic extrusion." Applicants respectfully submit that the process described by Feldbrugge involved simple extrusion. The differences between thermoplastic extrusion and simple extrusion are widely recognized, as described in the following quotations:

(1) "Extrusion is simply the operation of shaping a plastic or dough-like material by forcing it through a restriction or die." M.N. Riaz, Introduction to extruders and their principles, in *Extruders in Food Applications 1* (M.N. Riaz, ed., Technomic Publishing Co., Lancaster, PA, 2000).

(2) "Food extrusion has been practiced for over 50 years. Initially its role was limited to mixing and forming . . . Now, the food extruder is considered a high-temperature, short-time

bioreactor that transforms a variety of raw ingredients into modified intermediate and finished products." J.M. Harper, Food extruders and their application, in Extrusion Cooking 1 (Mercier, Linko & Harper, eds., American Assoc. Cereal Chemists, St. Paul, MN 1998).

(3) "Extrusion may be defined as forcing a pumpable product through a small opening to shape materials in a designated fashion. . . . A home cookie maker is a simple example of an extruder. . . . In many food extrusion processes, heating and cooking of raw materials occur as they are mixed and formed to produce essentially a finished product in a single operation." D.R. Heldman & R.W. Hartel, Food Extrusion, in Principles of Food Processing 253 (Chapman and Hall, New York 1997).

(4) "Thermoplastic extrusion is the process in which a low-water, powder-like raw material is pressed and heated simultaneously in a shear field, forced through a shaping die, and rapidly hardened by cooling. . . . Three main steps of many food technologies, i.e., mixing of food system components, shaping of a food system and fixing the form and structure of a given food product, can be successively and continuously accomplished within the extruder barrel and at the exit." V.B. Tolstoguzov, Thermoplastic extrusion-the mechanism of the formation of extrudate structure and properties, 70 J. Assoc. Official Analytical Chemists 417, 419-420 (1993).

The last of these definitions distinguishes thermoplastic extrusion from simple extrusion. Feldbrugge describes simple extrusion, because (1) mixing was carried out in a mixer, not in the extruder; and (2) the mixture was not forced through an extrusion die.

Even though Morimoto referred in 1982 to Feldbrugge as describing thermoplastic extrusion, Feldbrugge did not refer to its own process as thermoplastic extrusion, and the Feldbrugge process would not have been considered to be thermoplastic extrusion at the time the present application was filed due to a changed definition stemming from advances in the type of extruders in use.

(b) Feldbrugge Fails To Disclose Each and Every Limitation of the Claimed Invention

Further, Feldbrugge does not disclose or suggest each and every limitation of the presently claimed invention. With respect to claims 1 and 56, Feldbrugge does not disclose a thermoplastic extrusion product containing about 1-80% of food grade protein (or mixture of food grade proteins) and about 20-99% edible polysaccharide, where the food grade protein (or mixture of food grade proteins) comprises at least about 25% by weight of whey protein. Further with respect to claims 1 and 56, Feldbrugge does not disclose or suggest a thermoplastic extrusion product wherein the whey protein is undenatured.

With respect to claims 2 and 57, Feldbrugge does not disclose or suggest a thermoplastic extrusion product comprising about 15-65% by weight of food grade protein. Similarly, with respect to claims 3 and 58, Feldbrugge does not disclose or suggest a thermoplastic extrusion product comprising about 16-48% by weight of food grade protein.

With respect to claims 4 and 59, Feldbrugge does not disclose or suggest a thermoplastic extrusion product further comprising up to about 75% by weight of plant proteins, animal proteins, microbial proteins, or mixtures thereof.

With respect to claims 5-6 and 60-61, Feldbrugge does not disclose or suggest the thermoplastic extrusion products of the underlying base claims and intervening claims and further comprising wheat proteins.

With respect to claims 13 and 68, Feldbrugge does not disclose or suggest a thermoplastic extrusion product comprising at least about 50% by weight of whey protein.

With respect to claims 23-26 and 78-81, Feldbrugge does not disclose or suggest thermoplastic extrusion products wherein the whey protein comprised sweet whey solids, whey protein concentrate, whey protein isolate, or mixtures thereof.

With respect to claims 109-113 and 119, Feldbrugge does not disclose or suggest a thermoplastic extrusion product containing about 40-99% by weight of a whey protein concentrate and about 1-

60% by weight of an edible polysaccharide, where the whey protein concentrate comprises at least about 80% by weight of protein.

For these reasons, Feldbrugge fails to disclose each and every limitation of the presently claimed invention.

(c) Feldbrugge Fails To Enable Making or Using of
the Claimed Invention

Enclosed with this paper is the Declaration of Conly L. Hansen.

Dr. Hansen is an expert in the fields of food science and agricultural engineering due to his education, work experience on the faculties of Ohio State University and Utah State University for a total of about 27 years, original research, teaching, and other professional attainments. His declaration gives his opinion that the disclosure of Feldbrugge patent is not sufficient to enable a person of ordinary skill in the relevant art to make and use the invention. He further opines that, due to the insufficiency of the disclose in the Feldbrugge patent, it would not have been obvious to a person of ordinary skill in the art to bridge the gap between what is disclosed in Feldbrugge and what is claimed in the present application.

(d) Feldbrugge Fails To Support a Prima Facie Case of Obviousness

In view of the above, Applicant respectfully submit that a *prima facie* case of obviousness has not been established for failure to show each and every limitation of the presently claimed invention in the prior art and because Feldbrugge would not enable a person of ordinary skill in the art to make and use the presently claimed invention. Accordingly, withdrawal of the rejection is respectfully requested.

(3) Claims Rejected over the Combination of the Morimoto or Feldbrugge and Villagran References

Claims 17, 18, 72, 73, 114, and 115 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Morimoto or Feldbrugge taken together with Villagran.

The Morimoto and Feldbrugge patents were summarized above.

Villagran discloses a method of producing an extruded cereal-grain-based food product. In this process, the extruder is simply a mixer for forming a dough. There is no heating, and there is minimal shear in the extruder. The resulting sheet of dough is then cut into segments and fried (col. 1, lines 65-68). A gum may be added to the dough to prevent toothpacking.

The combination of Morimoto and Villagran fails to make up for the deficiencies of the Morimoto reference alone. Morimoto discloses the requirement of using denatured protein in the

composition that is subjected to thermoplastic extrusion. Claims 1 and 56 contain the limitation of using undenatured protein in the composition that is subjected to thermoplastic extrusion. Thus, the combination of Morimoto and Villagran fails to disclose or suggest each and every limitation of claims 1 and 56 and claims dependent thereof. Morimoto also fails to disclose or suggest using a whey protein concentrate comprising at least about 80% by weight of protein, and the combination of Morimoto and Villagran fails to make up for this deficiency. Thus, the combination of Morimoto and Villagran fails to disclose or suggest each and every limitation of claims 114 and 115.

The combination of Feldbrugge and Villagran fails to make up for the deficiencies of the Feldbrugge reference alone. That is, claims 17-18, 72-73, and 114-115 are dependent claims, and, as such, they incorporate by reference all of the limitations of their underlying base claims and intervening claims. The combination of Feldbrugge and Villagran fails to disclose each and every limitation incorporated by reference. Therefore, a *prima facie* case of obviousness has not been established with respect to these claims. Therefore, withdrawal of the rejection is respectfully requested.

(4) Claims Rejected over the Combination of the
Morimoto or Feldbrugge and JP 58-282325, Yackel,
or Ohyabu References

Claims 19-21, 74-76, and 116-118 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Morimoto or Feldbrugge taken together with JP 58-28235, Yackel, or U.S. Patent No. 4,430,356 ("Ohyabu").

Morimoto, Feldbrugge, and Yackel were described above.

JP 58-282325 discloses preparation of a food product by blending a milk-protein-containing hydrous gel with a dehydrating agent (such as sodium chloride, calcium chloride, calcium lactate, a monosaccharide, an oligosaccharide, a sugar alcohol, an amino acid or salt thereof, or lecithin) and a powdery dispersant (such as dextrin, cellulose powder, gum, white powder) while heating, followed by extruding and molding. The milk protein is from milk or defatted milk, or is casein.

Ohyabu discloses a method of making a formed food product of a microfibrillar milk protein. An aqueous gel of a milk protein (mainly calcium caseinate) is mixed with a dispersant, such as dextrin or sodium caseinate, and optionally fats and oils. The mixture is then formed into a selected shape to result in a product that, depending on the temperature and forming and mixing steps, can range from relatively soft, such as imitation cheese, to relatively hard, such as imitation jerky.

(a) Combination of Morimoto and JP 58-28235

The combination of Morimoto and JP 58-28235 fails to make up for the deficiency of Morimoto alone. Morimoto requires that the protein be denatured prior to extrusion. JP 58-28235 does not disclose the use of whey protein, but instead uses milk protein or casein. This combination of references fails to disclose or suggest using undenatured whey protein, as is claimed in the base claims of claims 19-21 and 74-76. With respect to claims 116-118, Morimoto fails to disclose using a whey protein concentrate that contains at least about 80% by weight of protein, and JP-5828235 fails to make up for this deficiency. Morimoto merely discloses use of "milk-whey protein," whatever that is. Thus, Morimoto fails to disclose each and every element of the invention claimed in independent claim 109 and its dependent claims. Moreover, it is respectfully submitted that Morimoto fails to provide an enabling disclosure of each and every element claimed in claims 116-118, because Morimoto's disclosure of "milk-whey protein" does not place a whey protein concentrate containing at least about 80% protein in possession of the public. Thus, the combination of Morimoto and JP 58-28235 fails to disclose or suggest the presently claimed invention.

(b) Combination of Morimoto and Yackel

The combination of Morimoto and Yackel also fails to make up for the deficiency of Morimoto alone. Morimoto requires the use of denatured protein prior to extrusion. Yackel requires high water content and a proteinaceous material, such as milk or whey. In this connection, it should be recognized that whey is not the same thing as whey protein. Concerning claims 19-21 and 74-76, the combination of Morimoto and Yackel fails to disclose or suggest using undenatured whey protein. Concerning claims 116-118, the combination of Morimoto and Yackel fails to disclose or suggest using a whey protein concentrate containing at least about 80% protein. Therefore, the combination of Morimoto and Yackel fails to disclose or suggest each and every limitation of the claimed invention.

(c) Combination of Morimoto and Ohyabu

The combination of Morimoto and Ohyabu also fails to make up for the deficiency of Morimoto. With respect to claims 19-21 and 74-76, the combination of Morimoto and Ohyabu fails to disclose or suggest using undenatured whey protein. Concerning claims 116-118, the combination of Morimoto and Ohyabu fails to disclose or suggest using a whey protein concentrate containing at least about 80% protein. Therefore, the combination of Morimoto and

Ohyabu fails to disclose each and every limitation of the claimed invention.

(d) Combination of Feldbrugge and JP 58-28235

The combination of Feldbrugge and JP 58-28235 fails to make up for the deficiencies of the Feldbrugge reference alone. As summarized above, Feldbrugge fails to disclose or suggest (1) with respect to claims 19-21 and 74-76, a thermoplastic extrusion product of a composition comprising about 1-80% food grade protein and 20-99% polysaccharide, wherein the food grade protein is at least about 25% whey protein, or (2) with respect to claims 116-118, a thermoplastic extrusion product of a composition comprising about 40-99% by weight of a whey protein concentrate and about 1-60% by weight of an edible polysaccharide, wherein the whey protein concentrate comprises at least about 80% by weight of protein. The combination of Feldbrugge and JP 58-28235 also fails to disclose each and every limitation of these claims.

(e) Combination of Feldbrugge and Yackel

The combination of Feldbrugge and Yackel also fails to make up for the deficiencies of Feldbrugge. The combination of Feldbrugge and Yackel fails to disclose or suggest (1) with respect to claims 19-21 and 74-76, a thermoplastic extrusion product of a composition comprising about 1-80% food grade

protein and 20-99% polysaccharide, wherein the food grade protein is at least about 25% whey protein, or (2) with respect to claims 116-118, a thermoplastic extrusion product of a composition comprising about 40-99% by weight of a whey protein concentrate and about 1-60% by weight of an edible polysaccharide, wherein the whey protein concentrate comprises at least about 80% by weight of protein. Hence, the combination of Feldbrugge and Yackel fails to disclose or suggest each and every limitation of the claimed invention.

(f) Combination of Feldbrugge and Ohyabu

The combination of Feldbrugge and Ohyabu also fails to make up for the deficiencies of Feldbrugge. The combination of Feldbrugge and Ohyabu fails to disclose or suggest (1) with respect to claims 19-21 and 74-76, a thermoplastic extrusion product of a composition comprising about 1-80% food grade protein and 20-99% polysaccharide, wherein the food grade protein is at least about 25% whey protein, or (2) with respect to claims 116-118, a thermoplastic extrusion product of a composition comprising about 40-99% by weight of a whey protein concentrate and about 1-60% by weight of an edible polysaccharide, wherein the whey protein concentrate comprises at least about 80% by weight of protein. Therefore, the combination of Feldbrugge and

Ohyabu fails to disclose or suggest each and every limitation of the claimed invention.

(5) Claims Rejected over the Combination of the Morimoto or Feldbrugge and Ohyabu

Claims 22, 77, 82, and 119 were rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Morimoto or Feldbrugge taken together with Ohyabu.

These claims are dependent on their base claims. As dependent claims, they incorporate by reference all of the limitations of the base claims.

As shown above, the combination of Morimoto and Ohyabu fails to disclose or suggest all of the limitations of any of claims 1, 56, and 109. As also shown above, the combination of Feldbrugge and Ohyabu fails to disclose or suggest all of the limitations of any of these independent claims. Therefore, these combinations of references also fail to disclose or suggest all the limitations of any of the dependent claims, and, in particular, of claims 22, 77, 82, and 119.

(6) Claims Rejected over the Combination of the Yackel and Villagran References

Claims 114 and 115 were rejected under 35 U.S.C. § 103(a) as allegedly being obvious over the combination of Yackel and Villagran.

Yackel was summarized above. Briefly, Yackel discloses extrudates that imitate "the tender, succulent textural properties of freshly cooked natural products such as cooked mushrooms and shellfish products." Abstr. These products are prepared by thermoplastic extrusion of proteinaceous materials that contain at least 110 parts by weight of water for each 100 parts by weight of proteinaceous material. Col. 2, lines 18-21. Yackel fails to disclose or suggest addition of polysaccharide to the proteinaceous material.

Villagran was also summarized above. Briefly, Villagran discloses extruded cereal-grain-based fried foods. In Villagran's process, the extruder is simply a mixer for forming a dough. There is no heating, and there is minimal shear in the extruder. The resulting sheet of dough is then cut into segments and fried (col. 1, lines 65-68). A gum, such as carboxymethyl cellulose, may be added to the dough to prevent toothpacking, and protein may be an optional component of the dough.

The combination of Yackel and Villagran fails to disclose an product made by extruding a composition containing about 40-99% by weight of a whey protein concentrate, which comprises at least about 80% by weight of protein, and about 1-60% by weight of edible polysaccharide. Thus, the combination of references fails to disclose or suggest each and ever limitation of the claimed invention.

Further, Applicants respectfully submit that there is no indication that the tender, succulent product of Yackel is subject to the problem of toothpacking, which is the stated reason that Villagran adds carboxymethyl cellulose to its gritty fried product, i.e., to reduce toothpacking. Further, a person of ordinary skill in the art interested in making a tender, succulent product would not look to teachings relating to a gritty, gummy, cereal-based fried food to solve a non-existent problem. Thus, there is no motivation to a person of ordinary skill in the art to combine the teachings of Yackel and Villagran.

(7) Claim Rejected over the Combination of the Yackel and Ohyabu References

Claim 119 was rejected under 35 U.S.C. § 103(a) as allegedly being obvious over the combination of Yackel and Ohyabu.

The teachings of Yackel and Ohyabu were summarized above. Briefly, Yackel discloses a tender, succulent product that imitates cooked mushrooms or shellfish products. Yackel's product is totally devoid of polysaccharide and fails to disclose a product containing about 40-99% by weight of a whey protein concentrate that contains at least about 80% by weight of protein. Ohyabu discloses a formed food product made from an aqueous gel composed mainly of calcium caseinate (which is not a

whey protein concentrate) mixed with a dispersant, such as dextrin or sodium caseinate, and optionally fats and oils.

The combination of Yackel and Ohyabu fails to disclose or suggest an extrusion product made from a composition comprising about 40-99% by weight of a whey protein concentrate, which comprises at least about 80% by weight of protein, and about 1-60% by weight of an edible polysaccharide. It is not clear what the combination of these two references suggest, but it is clear that it would not be the presently claimed invention.

(8) Cited References Were Not Considered in Their Entireties

References must be considered as a whole, including subject matter that teaches away from the invention as well as subject matter that suggests the invention, and not for their isolated teachings. *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 227 U.S.P.Q. 657, 669 (Fed. Cir. 1985).

Feldbrugge discloses a dense, fibrous product that simulates meat. Feldbrugge teaches mixing the ingredients in a mixer and then feeding the resulting dough through a simple heated extruder without the use of an exit die. There is substantial shear in the extrusion process. Therefore, when considered as a whole, Feldbrugge teaches away from mixing in the extruder and away from using an exit die, both of which teach away from the presently

claimed invention, but suggests using heat and shear forces in the extrusion process.

Villagran discloses a gritty, gummy cereal-grain-based fried food. In Villagran, the extruder is simply a mixer for forming a dough. There is no heating, and there is minimal shear in the extruder. The resulting sheet of dough is then cut into segments and fried. Therefore, when considered as a whole, Villagran teaches that the extruder is simply a mixer, that no heating is to take place in the extruder, and that the extruded product is to be fried.

JP 58-282325 discloses preparation of a food product by blending a protein-containing hydrous gel with a dehydrating agent and a powdery dispersant under heating, followed by extruding and molding.

Morimoto teaches extrusion of a denatured heat-coagulable protein mixed with a starch and an alkali metal sulfite.

Yackel discloses a tender, succulent product totally lacking in polysaccharide by high in water content.

Ohyabu describes a formed food product made from an aqueous gel composed mainly of calcium caseinate mixed with a dispersant, such as dextrin or sodium caseinate, and optionally fats and oils.

When considered in their entireties, Feldbrugge and Villagran contradict each other. One reference teaches to mix

the ingredients before placing them in the extruder, while the other reference teaches to mix the ingredients in the extruder. One reference teaches to heat the ingredients in the extruder, and the other references teaches not to heat in the extruder. One references teaches to exert substantial shear forces on the ingredients in the extruder, and the other reference teaches away from exerting substantial shear forces. Therefore, it is respectfully submitted that these two references, when considered in their entireties, teach away from each other. Hence, their combination is illegitimate for use as a basis for rejecting the instantly claimed invention.

Feldbrugge and JP 58-282325 both teach making meat-like products. The disclosure of JP 58-282325 is so brief and ambiguous that it is uncertain as to what it actually teaches. The ingredients are blended while being heated, then they are extruded and molded. However, it is not certain as to whether the blending takes place in the extruder or in a mixer, whether the heating takes place in the extruder or elsewhere, whether or not substantial shear forces are exerted on the blend, whether or not an exit die is used on the extruder, and so forth. JP 58-282325 teaches using casein or proteins from milk, not whey proteins.

Yackel teaches a tender, succulent product lacking polysaccharide, while Villagran teaches a gritty, gummy, grainy

fried food. It would be very unlikely that a person of ordinary skill in the art would combine these two references because of their divergent subject matter. Probably the only thing they have in common is they both relate to extruded foods.

What is a person of ordinary skill in the art to learn from these disclosures? It is not certain, but it is clear that whatever these combinations of references teach, it is not the presently claimed invention. The Office Action has picked and chosen isolated teachings from the cited references without guidance in the prior art to do so. This violates accepted procedure for making a determination under Section 103. For this reason, a *prima facie* case of obviousness is lacking.

(9) Hindsight Reconstruction of the Claimed Invention Using the Applicant's Description as a Blueprint Is Improper

The C.C.P.A. stated in In re Carroll, 202 U.S.P.Q. 571, 572 (C.C.P.A. 1979):

One of the more difficult aspects of resolving questions of non-obviousness is the necessity "to guard against slipping into use of hindsight." Graham v. John Deere Co., 383 U.S. 1, 36, 148 USPQ 459, 474 (1965). Many inventions may seem obvious to everyone after they have been made. However, 35 USC 103 instructs us to inquire into whether the claimed invention "would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." Thus, in deciding the issue of obviousness, we must look at the prior art presented from a vantage point in time prior to when the invention was made, and through the

eyes of a hypothetical person of ordinary skill in the art.

Moreover, it has been widely recognized that virtually every invention is a combination of elements and that most, if not all, of these will be found somewhere in an examination of the prior art. This reasoning led the Federal Circuit, in Connell v. Sears, Roebuck & Co., 220 U.S.P.Q. 193, 199 (Fed. Cir. 1983) to state:

The test is whether the claimed invention as a whole, in light of all the teachings of the references in their entirety, would have been obvious to one of ordinary skill in the art at the time the invention was made.

Still further, the Federal Circuit stated as follows:

Obviousness is tested by "what the combined teachings of the references would have suggested to those of ordinary skill in the art." *In re Keller*, 642 F.2d 413, 4225, 208 USPQ 871, 881 (CCPA 1981). But it "cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination." *ACS Hosp. Sys.*, 732 F.2d at 1577, 221 USPQ at 933. And "teachings of references can be combined *only* if there is some suggestion or incentive to do so." *Id.* Here, the prior art contains none.

Instead, the Examiner relies on hindsight in reaching his obviousness determination. But this court has said, "To imbue one of ordinary skill in the art with knowledge of the invention in suit, when no prior art reference or references of record convey or suggest that knowledge, is to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher." *W.L. Gore*, 721 F.2d at 1553, 220 USPQ at 312-13. It is essential that "the decisionmaker forget what he or she

has been taught at trial about the claimed invention and cast the mind back to the time the invention was made . . . to occupy the mind of one skilled in the art who is presented only with the references, and who is normally guided by the then-accepted wisdom in the art." *Id.* One cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention.

In re Fine, 837 F.2d 1071, 5 USPQ2d 1596, 1599-1600 (Fed. Cir. 1988).

These cases make it clear that if the PTO is to establish a *prima facie* case of obviousness, it is not sufficient to merely assert that "it would be obvious."

Applicant respectfully submits that if one follows the above guidelines and analyzes the art properly, then there is no suggestion of the invention as claimed. The Office Action has picked certain disclosures of the cited references, ignoring others, without guidance from the prior art to do so. This is exactly the type of hindsight reasoning that is forbidden by the law. For this reason, Applicants respectfully submit that a *prima facie* case of obviousness has not been established.

(10) The Requirements of *Graham v. John Deere* Have Not Been Followed

Graham v. John Deere requires that the scope and content of the prior art be determined, the differences between the prior art the claimed invention be set out, and the level of ordinary skill in the art be determined.

In the present instance, the scope and content of the prior art has been given short shrift, because the references were not considered in their entireties. The inconsistencies and contradictory teachings of the references were ignored. Isolated teachings were selected, while other teachings were likewise ignored. Similarly, the differences between the cited references and the claimed invention have been largely ignored or glossed over. Further, the level of skill in the art has not been established. It is legally and logically impossible to make a determination that a claimed invention would or would not have been obvious to a person of ordinary skill in the art when the level of skill of the person of ordinary skill in the art has not been established.

Therefore, it is respectfully submitted that proper procedure has not been followed. For this reason, a *prima facie* case of obviousness has not been established.

(11) Conclusion Concerning Nonobviousness

For all the reasons specified above, it is respectfully submitted that a *prima facie* case of obviousness has not been established concerning any claim. Withdrawal of the rejections is respectfully requested. Even if a *prima facie* case of obviousness had been established, the preponderance of the evidence weighs in favor of the patentability of the presently

claimed invention. The cited references, alone or in combination, fail to teach each and every limitation of the claimed invention. The cited references were not considered in their entirety. The cited references teach away from making the presently claimed invention and from being combined. Improper hindsight reconstruction of the invention was used. Moreover, the mandates of *Graham v. John Deere* were not carried out. Therefore, withdrawal of the grounds of rejection is respectfully requested.

V. Conclusion

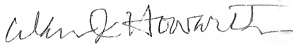
Should the Examiner deem it advisable to conduct a telephone interview for any reason, the undersigned attorney would be most agreeable to receiving a telephone call to expedite the prosecution of the application.

For the reasons given above, Applicants respectfully request reconsideration and allowance of Claims 1-6, 13-26, 56-61, 68-81, 109, and 111-119 and passage of this application to issue.

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Respectfully submitted,



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